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EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/745,095	APPEL ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *58-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,7-9,12,15-32,44,49-51,56,57,63,65-81,88-97,101,103-108,120-122,124,130 and 131* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 2,7-9,12,15-32,44,49-51,56,57,63,65-81,88-97,101,103-108,120-122,124,130 and 131.

DETAILED ACTION

Receipt for Amendments/Remarks and the Information Disclosure Statement received on 12/23/05 and the Information Disclosure Statement field 8/1/05 is acknowledged. Claims **2, 7-9, 12, 15-32, 44, 49-51, 56, 57, 63, 64-81, 88-97, 101, 103-108, 120-122, 124, 130 and 131** are pending in this application. Claims 58-62 stand withdrawn as being directed to a nonelected species.

Claim Objections

The objection to claims 64-66 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in view applicant's arguments which are persuasive.

Claim Rejections - 35 USC § 112

The rejection of claims 118-119 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the cancellation of claims 118-119.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 7-9, 12, 15-32, 44, 49-51, 56, 63, 65-81, 88-97, 101, 103-108, 120-122, 124, and 130-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al (4,765,989) in view of Stevens et al (5,897,874), optionally in further view of Park et al (6,271,278).

Wong et al teach an osmotic device for administering drugs in various shapes and forms (tablets and capsules). See figures. The object of the device is to provide a therapeutic device that administers a complete pharmaceutical regimen at a controlled and continuous time period. The device also provides dispending to the gastric tract at a controlled rate. See column 3. The device contains a first composition containing a drug, polyethyleneoxide (PEO) (drug entertaining agent), hydroxypropylmethylcellulose (HPMC) (concentration enhancing polymer), and magnesium stearate. The second expanding composition contains PEO (swelling agent), instant HPMC (tabletting aid), sodium chloride, and magnesium stearate. Nifedipine is utilized in the examples, which is a low-solubility drug and the drug is not in a solid dispersion form. See examples, especially 3. The osmopolymers are swellable and hydrophilic polymers, which swell and expand in aqueous medium. See column 15, lines 61-68. The osmopolymers used in the invention have an expansion and are utilized in both the firstly layer and second layer, which may be different or the same (col. 16, lines 3-5). The osmopolymers utilized may be a variety of hydrophilic polymers such as PEO polymers or a mixture of methylcellulose, crosslinked agar and carboxymethyl cellulose. See column 16, lines 20-23 and line 36. The mass ratio of the first

composition to the second composition is taught on column 16. The general concept of swelling ratio is taught on columns 17 and 18. Wong teaches the active agent may in various forms and dispersed in suspending agents such as PVP (col. 18, line 43 to col.19, line 5). Agents such as tartaric acid (solubilizers), mannitol (fluidizers), sucrose, and sodium chloride are taught. The reference teaches a semipermeable wall that allows water to enter the core. A semipermeable wall made of 95% cellulose acetate having an acetyl content of 39.8% and 5% PEG surrounds the two compositions. The coating has pore sizes of 10 angstorm to 100 microns See column 10 to column 11, line 20. . Solvents for the semipermeable membrane are taught on column 20, lines 11-35. Release of the drug is taught in Figure 9. Wong teaches several shapes such as in Figure 5, wherein rather than have one port as seen in a tablet, the device as several pores to allow the passage of water. Wong teaches that the shape of the tablet and capsule shape are different, but they act in a similar manner to let fluid into the core. See column 8-9. Solvents for the semipermeable membrane are taught on column 20, lines 11-35. Release of the drug is taught in Figure 9.

Wong does not teach the instant swelling agents (sodium starch glycolate or croscarmellose) which provide the instant parameters (the instant swelling ratio and core strength). Furthermore, Wong does not teach the instant amount of tableting aid.

Stevens et al teach a delivery device with a drug and expandable excipient. The dosage form may be in tablet form. See abstract and examples. The device has an impermeable coating formed from a water-soluble material, which is preferably but not limited to capsules wherein the capsule contains the expandable excipient. See column 3, lines 13-21. The expandable excipients may also be used in a solid pharmaceutical dosage forms such as compressed powders (tablets)

or cast forms. See column 4, lines 1-6. The expandable excipient is made of a solid material whose volume increases due to the absorption of water from the surrounding medium and has a water-swellable material that has the overall swelling capacity of 200-400% (col. 4, lines 44-48). The swellable materials may be chosen from water-swellable hydrogel polymers: PEO polymers with a molecular weight of 4,000-12,000 or known pharmaceutical disintegrants, i.e. sodium starch glycolate, microcrystalline cellulose, etc., which swell rapidly and completely after administration, thereby disrupting or breaking up the solid dosage form. Stevens teaches disintegrants are not only conventionally used in solid dosages forms but they are known to enhance the delivery rate of active substances. See column 4, lines 10-30. The expandable excipients also contain wetting agents (sodium lauryl sulfate) up to 2%, lubricants such as magnesium stearate and silica up to 1%, and water-soluble sugars up to 10%. Stevens teaches the conventional hardness of a tablet is 4kg and the instant tablet may have the strength of conventional tablets or less, i.e. 2kg (col. 5, lines 5-70). The drug may be mixed with a carrier material and is positioned over the hydrogel layer (col. 6, lines 26-27). The swelling factor is taught on column 7. The device has the advantage of containing expandable excipients that are designed to improve the expulsion of the active in a particular region such as the gastric tract that has low water content. See column 5. Example 10 discloses a disintegrant tablet (the disintegrants are compressed to form a tablet) containing 24% low-substituted cellulose (L-HPC), 24% Avicel (microcrystalline cellulose), and 50% EXPLOTAB (sodium starch glycolate). Note both L-HPC and Avicel read on the tabletting aid. This combination of Avicel and EXPLOTAB in example 10 provide for instant swelling ratio.

Park et al teach a hydrogel composition having fast swelling and high mechanical strength. The superporous hydrogel composite is formed by polymerizing one or more ethylenically-unsaturated monomers, and a crosslinking agent, in the presence of particles of a disintegrant. The disintegrant such as crosslinked sodium carboxymethylcellulose, crosslinked sodium starch glycolate, and crosslinked PVP, rapidly absorbs water and serves to increase mechanical strength. See abstract. Park discloses that the limiting factor of hydrogels have been their slow swelling property which usually takes several hours and this it too slow for many applications when fast swelling is essential. Park discloses that although hydrogels have been successfully used as gastric retention devices that stay in the stomach for several hours, the hydrogels have to be preswollen before administering to avoid premature emptying into the intestine. Further, Park discloses to increase swelling properties, the mechanical strength decreases; however by adding the disintegrant, the mechanical strength is increased. See column 4, lines 10-45 and column 26. Swelling ratios are taught on Table 2. Compression is taught in Figure 4A in kg/cm2. Park teaches that in the controlled drug delivery area superporous hydrogel and superporous hydrogel composites can be used as a platform for long-term oral drug delivery. See column 32, lines 40-50.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Wong et al and Steven et al and utilize the instant swelling agent. Firstly, one would have been motivated to utilize the instant swelling agent in the expandable hydrogel portion of Wong's since Stevens et al disclose the advantages of the instant swelling agent, i.e. the swelling capacity of the instant agents improve the release of an active in the gastro-intestinal tract, i.e. to provide for the complete release of the active from the dosage

form. It is the examiner's position that the selection of disintegrants versus hydrogels is obvious to a skilled artisan since both hydrogels and disintegrants are utilized in the art for the same purpose, i.e. the "push" of the active out of the body and they are characterized by a specific swelling capacity to yield a certain swelling ratio. Therefore, since the swelling capacity/ratio determines the rate of release of the active agent from the device, i.e. the "push" of the active out of the dosage form, it is prima facie obvious to manipulate the selection of the swelling agent(s) and amount to yield a desired release rate. Lastly, one would expect similar results since Wong's expandable portion contains PEO polymers and Stevens teaches that the expandable layer may be a hydrogel such as a PEO polymer or in an *alternative embodiment* the PEO polymers may be substituted with the instant swelling agent called disintegrants to enhance to rate of deliver since the instant swelling agent rapidly absorb water.

Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further look at Park et al and select the instant swelling agents over a hydrogel. One would have been motivated to do so since Park discloses that a fast swelling and superswelling hydrogel is important for controlled oral dosage forms, however prior art hydrogels have decreased mechanical strength as the swelling capacity is increased. Thus, Park states that instant swelling agents are improvement since they not only possess super swelling capacity but also provide increased mechanical strength to hydrogels. Therefore, one would have been motivated to utilize the instant swelling agent to not only increase the swelling capacity of the hydrogel but also increase the mechanical strength. Furthermore, Park's teachings support the examiner's position that Stevens's expandable excipient implicitly has the instantly claimed strength.

Response to Arguments

Applicant's arguments filed 12/23/05 have been fully considered but they are not persuasive.

Applicant argues that the examiner is incorrect and Wong does not teach the instant mass ratio of the drug layer to the water-swellable polymer layer. Applicant further argues that Wong does not teach the importance for the drug composition to have a higher mass than the swelling layer, which maximizes the drug loading into the tablet.

The examiners notes and acknowledges that the wrong column was cited to teach the mass ratio of the drug composition to water-swellable composition. However, the examiner points to example 13 wherein Wong teaches the drug layer weight 150mg and the expandable layer weight 100mg. Thus Wong clearly teaches a device wherein the drug layer has a higher mass than the water-swellable layer.

Applicant argues that the examiner's has improperly utilized the applicant's own disclosure to provide the motivation to combine the references. Applicant argues that there is not motivation to combine a reference directed to a tablet with a reference directed to a capsule. Applicant argues that Stevens teaches a long list of suitable hydrogels and disintegrants; hence there is no motivation to utilize the instant two swelling agents in particular. It is argued that a skilled artisan might equally be motivated to utilize any other disintegrant taught by Stevens. Applicant argues that Stevens teaches the use of the swelling agents for capsules and the instant invention does not relates to capsules. Lastly, applicant argues that Stevens is not concerned with tablet hardness and teaches away from tablet hardness.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In instant case, Stevens demonstrates that the use of the instant swelling agents are known to those skilled in the art at the time the invention was made. Note column 4, lines 10-17.

> **Disintegrants are known pharmaceutical expedients** and are often included in solid dosage form (such as **tablets** or pessaries) in order to enhance the rate of delivery of an active substance contained therein. The disintegrants are water-swellable substances which absorb water after administration to a patient and swell rapidly, thereby disrupting or breaking-up the solid dosage form.

Clearly, the use of the instant swelling agents in tablets is not novel. Thus, the examiner has demonstrated that the instant invention is obvious to those skilled in the art and reconstruction is proper since the knowledge was not gleaned from the applicant's disclosure, rather it was known at the time the instant invention was made.

Stevens teaches the expandable excipient (swelling agent) may be chosen from 1) hydrogels or 2) disintegrants wherein the disintegrants include the instantly claimed sodium starch glycolate. Stevens provides the motivation to substitute Wong's PEO hydrogel by teachings PEO polymers may be substituted with disintegrants since disintegrants rapidly absorb water and thus enhance the rate of delivery of the drug. Therefore, the motivation to utilize the instant swelling agents over Wong's hydrogel is found in Stevens' disclosure *itself*. Further, although Stevens teaches different swelling agents, the instant swelling agent and instant

tabletting aid in the instant concentration are disclosed in example 10 for a tablet. Therefore, Stevens' exemplification of the EXPLOTAB (sodium starch glycolate) clearly directs a skilled artisan to utilize the instant swelling agent. Additionally, the examiner relies on Park to further provide the motivation to select the instant swelling agents over the hydrogels taught by Stevens. Park states that the instant swelling agents provide mechanical strength to the tablet unlike hydrogels. Thus, Park provides further motivation to select instant sodium starch glycolate over the other expandable agents taught by Stevens. Thus, skilled artisan would have been motivated *after* looking at Wong and Stevens to specifically utilize the instant swelling agents for the advantages taught by not only Stevens but also Park.

With regard to the combination of a tablet reference and capsule reference, this has been addressed in the last office action. The examiner again points out that Wong's device may be formulated into a capsule or tablet; thus tablet and capsule formulations are not non-analogous art as argued by applicant. Applicant argues that the tabletting art has different problems such as friability, breakage, etc. that the capsule art does not. The examiner points out that the expandable excipient taught in Stevens is first made into a tablet form (the disintegrants are compressed to form the tablet) and *then* placed in a capsule. See example 10. Therefore, the intermediate form is in fact a tablet and the problems that occur in the tablet art would still be applicable. Although Stevens teaches a capsule shell, the instantly claimed swelling polymer is not in the capsule shell, rather and as pointed out above, it is made separately and then placed in the shell. Secondly, the examiner points out that both Wong's expandable excipient and Stevens' expandable excipient function in a similar manner, i.e. to swell and push the active out of the dosage form. Moreover, Wong also states that although capsules and tablets have different

shapes, they act in a similar manner to let fluid into the core. See column 8-9. Therefore, the characteristic of the swelling polymer will remain the same regardless of its formulation into a capsule or tablet.

Applicant argues that Stevens does not teach the instant swelling agent with the tabletting aid in 20% in a tablet form. Applicant argues that again the examiner has used impermissible hindsight and the examiner has used the applicant's own disclosure to make the rejection.

The examiner points out that Stevens teaches the disintegrant **tablet** comprises 24% low-substituted cellulose (L-HPC), 24% Avicel (microcrystalline cellulose), and 50% EXPLOTAB (sodium starch glycolate). Note both L-HPC and Avicel read on the tabletting aid. Thus, Stevens in fact teaches the swelling agent and the tabletting agent in a tablet form and applicant's argument that the examiner needs a motivation to utilize a tabletting aid in the instantly claimed concentration is moot.

With regard to the unexpectedness of the tablet strength and swelling ratio, again the examiner points out that the applicant has not provided any evidence to overcome obviousness. Firstly, it is noted that Table 12 of applicant's specification discloses that EXPLOTAB and MCC provide instant swelling ratio and the examiner points out that Stevens utilizes the same combination in example 10; thus Stevens' combination of EXPLOTABLE and MCC would also have the instant swelling ratio.

With regard to the tablet hardness it is the examiner's position that the core strength would implicitly flow from the combined teachings of Wong and Stevens. The examiner strongly suggests the applicant provide a showing of unexpected results to overcome the rejection based on obviousness.

Applicant argues that Parks is concerned with different swelling material than that of the instant invention. Applicant argues that Park is not concerned with tablet or compressed tablets. Applicant argues that Park is concerned with a different problem.

Again as pointed out in the previous response, it is the examiner's position that Wong in view of Stevens is sufficient to render the instant invention prima facie obvious. The examiner relies on Park to provide further motivation to select instant sodium starch glycolate and sodium croscarmellose since Park states that the instant swelling agents provide mechanical strength to the tablet unlike hydrogels. The examiner further points out that Park teaches the composites for controlled release of drugs (see column 32, lines 40-50) which is the same field of endeavor as Wong and Stevens. Park also discloses on column 23, lines 55-60:

> Superdisintegrants, such as Ac-Di-Sol.RTM., Primojel.RTM., Explotab.RTM., and Crospovidone.RTM. **have been used extensively in tablets and capsules to promote their fast disintegration.** The mechanism of disintegration is based on swelling, wicking, and deformation of the disintegrants [Kanig, J. L. et al., 1984]. When a compressed tablet is placed in aqueous solution, water can be quickly absorbed, and the swelling of the disintegrant breaks apart tablets quickly.

Thus, it can be seen that Park teaches the conventional use of the instantly claimed swelling agents and demonstrates the level of skill at the time the instant invention was made.

Claim 57 is rejection under 35 U.S.C. 103(a) as being unpatentable over Wong et al (4,765,989) in view of Stevens et al (5,897,874), optionally in further view of Park et al (6,271,278), in further view of From hypertension to angina to Viagra (Jim Kling, Modern Drug Discovery, 1998, 1(2), pg.31, 33-34, 36, 38).

As set forth above, Wong and Stevens teach delivery devices containing expandable excipients. Wong teaches the suitability of several drugs such as antihypertensives.

Wong and Stevens do not teach instant drug

Kling teaches Viagra as a drug for hypertension or erectile dysfunction.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use sildenafil citrate in the device of Wong or Stevens. One would be motivated to do so if one wanted to treat erectile dysfunction and it is obvious for an artisan to choose the drug depending on the symptoms and disease to be treated. Further, one would be motivated to do so with the expectation of similar results since Wong teaches the use of antihypertensives in the device.

Response to Arguments

Applicant argues that King does not cure the fatal flaws of Wong et al and Stevens et al.

Applicant's arguments filed 12/23/05 have been fully considered but they are not persuasive. The merits of Wong et al and Stevens et al have been discussed above. The examiner merely relies on King to teach the instant active agent. The choice of the active agent depends on the symptoms to be treated. Therefore, if one were motivated to treat erectile dysfunction and hypertension, then one would utilize the instant active agent.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 2, 7-9, 12, 15-32, 44, 49-51, 56, 57, 63, 64-81, 88-97, 101, 103-108, 120-122, 124, 130 and 131 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-20 of copending Application No. 10/344171 is withdrawn.

The examiner has withdrawn the rejection for the following reason: copending application '171 is directed to the broader scope (a controlled release drug dosage form comprising a core wherein the core comprises: a drug containing composition and a water-swellable composition in separate regions) whereas the instant application is directed to specific excipients and specific tablet parameters (swelling ratio, tablet hardness, etc), i.e. components (a) to (l). Although copending application does claim *some* overlapping components, ' 171 does not claim the combination of (a) to (l).

It should be noted that this rejection will be re-instated if during prosecution of application 10/344171, if this patentable distinction is not maintained. It should be noted though the claims 10/344171 have double patenting issues over the instant application since the claims of '171 encompass the subject matter of the instant claims.

Claim 2, 7-9, 12, 15-32, 44, 49-51, 56, 57, 63, 64-81, 88-97, 101, 103-108, 120-122, 124, 130 and 131 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 09/745096 now issued US 6,899896. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant application is directed to controlled release drug dosage form comprising a core wherein the core comprises: a drug containing composition and a water-swellable composition in

separate regions. The drug composition contains a low-solubility drug and drug-entraining agent. The swelling composition further contains at least 20% tableting aid and swelling agent. The tablet has water-permeable, water-insoluble coating with a port there through.

Co-pending application is directed to controlled release drug dosage form comprising a core wherein the core comprises: drug containing composition and a water-swellable composition in separate regions. The drug composition contains a sertraline and drug-entraining agent. The tablet has a water-permeable, water-insoluble coating with a port there through.

Instant application and co-pending application are directed to a controlled release dosage form with a core that a separate swelling composition and drug composition. The difference between co-pending applications is that US patent is directed to a specific drug (sertraline) and instant application is directed to a generic low-solubility drug. The instant specification discloses sertraline as a low-solubility drug. Therefore, co-pending application and instant application having overlapping subject matter.

Response to Arguments

Applicant's arguments filed 12/23/06 have been fully considered but they are not persuasive.

Applicant argues that that the instant invention claims a specific core strength, a specific swelling ratio, and a specific tabletting aid in a specific weight percent.

The instant tabletting aid may be selected from lactose, xylitol, microcrystalline cellulose, HPC, MC, and HPMC and claim 11 of US '896 claims xylitol. The manipulation of the concentration is considered obvious absent the unexpectedness of the tabletting aid. The examiner points out that claim 76 of US '896 is directed to a tablet hardness that is provided by

an equation. The specification discloses the equation provides a tablet hardness of 6-12 KP. See column 23, lines 1-10. Note the disclosure of the patent may be used to define a terminology in the claims and in instant case, the disclosure defines the equation.

Pertinent Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,706,283 and application 10/799536 have been considered for double patenting issues. However, US patent '283 and application '536 do not have overlapping subject matter with the instant application for the following reasons: Firstly, the instant application is directed to a controlled release device with core comprising a separate region for a drug composition and a water-swellable composition respectively. Thus, '283 and '536 differs from the instant application in that although US '283 and copending '536 claims are directed to a controlled release device, the device does not have a separate region for a drug composition and the water-swellable composition respectively. Secondly, the instant application differs from US Patent and co-pending application in that the drug is not in a solid dispersion form. '283 and '536 are both *specifically* directed to a drug in a solid dispersion form.

Conclusion

None of the claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER